

AMENDMENTS TO THE CLAIMS

1) (Currently amended) ~~[An improved]~~ A multi-layered osmotic device for the controlled delivery of one or more active agents to one or more environments of use wherein the osmotic device comprises:

- a) a compressed core comprising a first active agent and an osmotic agent for controlled and continuous release of the ^[drug] first active agent;
 - b) a semipermeable membrane surrounding the core and having a preformed passageway therein, said semipermeable membrane being permeable to a fluid in the environment of use and substantially impermeable to the ~~[drug]~~ first active agent;
 - c) an inert, completely erodible or water soluble polymer coat comprising poly(vinylpyrrolidone)-(vinyl acetate) copolymer partially or substantially completely surrounding the semipermeable membrane and plugging the passageway in the ^[wall] semipermeable membrane; and
 - d) an external coat comprising a second active agent for immediate release of the ^[drug] second active agent, wherein the first active agent is released from the core after the polymer coat has partially or completely dissolved or eroded, and the first and second active agents are released into the same or different environments of use to provide a controlled delivery of the one or more active agents.
- 2) (original) An osmotic device according to claim 1 wherein the compressed core further comprises poly(vinylpyrrolidone).
- 3) (original) An osmotic device according to claim 1 wherein the semipermeable membrane consists essentially of cellulose acetate and poly(ethylene glycol).
- 4) (original) An osmotic device according to claim 1 wherein the external coat comprises poly(vinylpyrrolidone) and poly(ethylene glycol).
- 5) (original) An osmotic device according to claim 1 wherein the second active agent in the external coat comprises a therapeutic agent.
- 6) (original) An osmotic device according to claim 1 wherein the first active agent in the core comprises a therapeutic agent.
- 7) (original) An osmotic device according to claim 1 wherein the second active agent in the external coat comprises a therapeutic agent and the first active agent in the core comprises a therapeutic agent.

- 8) (original) An osmotic device according to claim 7 wherein the first and second active agents are the same.
- 9) (original) An osmotic device according to claim 8 wherein the first and second active agents are theophylline.
- 10) (original) An osmotic device according to claim 1 wherein the second active agent in the external coat comprises a therapeutic agent and the first active agent in the core comprises a different therapeutic agent.
- 11) (original) An osmotic device according to claim 10 wherein the first active agent is pseudoephedrine and the second active agent is loratadine.
- 12) (original) An osmotic device according to claim 10 wherein the first active agent is ranitidine and the second active agent is a combination of ranitidine and cisapride.
- 13) (original) An osmotic device according to claim 10 wherein the first active agent is pseudoephedrine and the second active agent is astemizole.
- 14) (original) An osmotic device according to claim 10 wherein the first active agent is diltiazem and the second active agent is enalapril.
- 15) (original) An osmotic device according to claim 1, wherein the one or more environments of use comprises a first environment of use and a different second environment of use.
- 16) (original) An osmotic device according to claim 15, wherein the first environment of use is the gastric region and the second environment of use is farther down the gastrointestinal tract of a mammal.
- 17) (original) An osmotic device according to claim 1, wherein the first and second active agents are released into the same environment of use.
- 18) (original) An osmotic device according to claim 1, wherein the controlled delivery of one or more active agents includes one or more of pH-dependent, pH-independent, diffusion controlled, dissolution controlled, pseudo-zero order, zero-order, pseudo-first order, first-order, second-order, rapid, slow, delayed, timed, and sustained delivery.
- 19) (original) An osmotic device according to claim 1, wherein at least a portion of the polymer coat dissolves or erodes in fluid present in an environment of use after the external coat has at least partially dissolved in an environment of use.

- 20) (original) An osmotic device according to claim 1, wherein the polymer coat is one or more of soluble in the same environment of use in which the external coat is soluble, and soluble in the same environment of use in which the core is soluble.
- 21) (original) An osmotic device according to claim 1, wherein the semipermeable membrane comprises a plasticizer and one or more of a cellulose ether, cellulose ester and cellulose-ester-ether.
- 22) (original) An osmotic device according to claim 1, wherein the external coat further comprises poly(vinylpyrrolidone).
- 23) (original) An osmotic device according to claim 1, wherein the polymer coat further comprises one or more of talc and poly(ethylene glycol).
- 24) (Currently amended) A multi-layered osmotic device for the controlled delivery of one or more active agents to one or more environments of use wherein the osmotic device comprises:
- a) a compressed core comprising a first active agent and an osmotic agent for controlled and continuous release of the first active agent;
 - b) a semipermeable membrane surrounding the core and having a preformed passageway therein, said semipermeable membrane being permeable to a fluid in the environment of use and substantially impermeable to the first active agent;
 - c) an inert, completely erodible or water soluble polymer coat partially or completely surrounding the semipermeable membrane and plugging the passageway in the semipermeable membrane; and
 - d) an external coat applied to and covering the inert polymer coat and comprising a second active agent for immediate release of the second active agent, wherein the first active agent is released from the core after the polymer coat has partially or completely dissolved or eroded, and the first and second active agents are released into the same or different environments of use to provide a controlled delivery of the one or more active agents.
- 25) (Currently amended) A multi-layered osmotic device for the controlled delivery of one or more active agents to one or more environments of use wherein the osmotic device comprises:

- a) a compressed core comprising a first active agent and at least one osmotic agent for controlled and continuous release of the first active agent;
 - b) a semipermeable membrane surrounding the core and having at least one preformed passageway therein;
 - c) an inert, completely erodible or water soluble polymer coat partially or completely surrounding the semipermeable membrane and plugging the passageway in the semipermeable membrane; and
 - d) an external coat applied to and covering the inert polymer coat and comprising a second active agent for immediate release of the second active agent, wherein the first active agent is released from the core after the polymer coat has partially or completely dissolved or eroded, and the first and second active agents are released into the same or different environments of use.
- 26) (Currently amended) A multi-layered osmotic device for the controlled delivery of one or more active agents to one or more environments of use wherein the osmotic device comprises:
- a) a compressed core comprising a first active agent and at least one osmotic agent for controlled and continuous release of the first active agent;
 - b) a semipermeable membrane surrounding the core and having at least one preformed passageway therein;
 - c) an inert, completely erodible or water soluble polymer coat partially or completely surrounding the semipermeable membrane and plugging the at least one preformed passageway in the semipermeable membrane; and
 - d) an external coat applied to and covering the inert polymer coat and comprising a second active agent for release of the second active agent, wherein the first active agent is released from the core after the polymer coat has partially or completely dissolved or eroded, and the first and second active agents are released into the same or different environments of use.
- 27) (Currently amended) A multi-layered osmotic device for the controlled delivery of one or more active agents to one or more environments of use wherein the osmotic device comprises:

- a) a compressed core comprising a first active agent and at least one osmotic agent for controlled and continuous release of the first active agent;
 - b) a semipermeable membrane surrounding the core and having at least one preformed passageway therein;
 - c) an inert, completely erodible or water soluble polymer coat partially or completely surrounding the semipermeable membrane and plugging the at least one preformed passageway in the semipermeable membrane; and
 - d) an external coat applied to and covering the inert polymer coat and comprising a second active agent for immediate, rapid, delayed, slow, sustained, pseudo-first order, pseudo-zero order, timed, controlled or combination thereof release of the second active agent, wherein the first active agent is released from the core after the polymer coat has partially or completely dissolved or eroded, and the first and second active agents are released into the same or different environments of use.
- 28) (Previously presented) The multi-layered osmotic device of claim 24, 25, 26 or 27, wherein the first and second active agents each comprise a therapeutic agent.
- 29) (Previously presented) The multi-layered osmotic device of claim 24, 25, 26 or 27, wherein the first and second active agents are the same.
- 30) (Previously presented) The multi-layered osmotic device of claim 24, 25, 26 or 27, wherein the first and second active agents are different.
- 31) (Previously presented) The multi-layered osmotic device of claim 24, 25, 26 or 27, wherein the first and second active agents are released into different environments of use.
- 32) (Previously presented) The multi-layered osmotic device of claim 24, 25, 26 or 27, wherein the first and second active agents are released into the same environment of use.
- 33) (Previously presented) The multi-layered osmotic device of claim 24, 25, 26 or 27, wherein the controlled delivery of one or more active agents includes one or more of pH-dependent, pH-independent, diffusion controlled, dissolution controlled, pseudo-zero order, zero-order, pseudo-first order, first-order, second-order, rapid, slow, delayed, timed, and sustained delivery.
- 34) (Previously presented) The multi-layered osmotic device of claim 1, 24, 25, 26 or 27, wherein the first and second active agents are independently selected at each occurrence from the group consisting of antibacterial, antihistamine, decongestant, anti-inflammatory,

We claim:

a) a compressed core comprising a first active agent and an osmotic agent for controlled and continuous release of the drug first active agent

b) a semipermeable membrane surrounding the core and having a preformed passageway therein, said membrane being permeable to a fluid in the environment of use and substantially impermeable to the first active agent;

c) an inert, completely erodible water soluble polymer coat comprising poly(vinylpyrrolidone)-(vinyl acetate) copolymer partially or substantially completely surrounding the semipermeable membrane and plugging the passageway in the wall; and

d) an external coat comprising a second active agent for immediate release of the drug wherein the first active agent is released from the core after the polymer coat has partially or completely dissolved or eroded, and the first and second active agents are released into the same or different environments of use to provide a controlled delivery of the one or more active agents.

2. An osmotic device according to claim 1 wherein the compressed core further comprises poly(vinylpyrrolidone).

3. An osmotic device according to claim 1 wherein the semipermeable membrane consists essentially of cellulose acetate and poly(ethylene glycol).

4. An osmotic device according to claim 1 wherein the external coat comprises poly(vinylpyrrolidone) and poly(ethylene glycol).

5. An osmotic device according to claim 1 wherein the second active agent in the external coat comprises a therapeutic agent.

6. An osmotic device according to claim 1 wherein the first active agent in the core comprises a therapeutic agent.

7. An osmotic device according to claim 1 wherein the second active agent in the external coat comprises a therapeutic agent and the first active agent in the core comprises a therapeutic agent.

8. An osmotic device according to claim 7 wherein the first and second active agents are the same.

10. An osmotic device according to claim 1 wherein the second active agent in the external coat comprises a therapeutic agent and the first active agent in the core comprises a different therapeutic agent.

11. An osmotic device according to claim 10 wherein the first active agent is pseudoephedrine and the second active agent is loratadine.

12. An osmotic device according to claim 10 wherein the first active agent is ranitidine and the second active agent is a combination of ranitidine and cisapride.

13. An osmotic device according to claim 10 wherein the first active agent is pseudoephedrine and the second active agent is astemizole.

14. An osmotic device according to claim 10 wherein the first active agent is diltiazem and the second active agent is enalapril.

15. An osmotic device according to claim 1, wherein the one or more environments of use comprises a first environment of use and a different second environment of use.

16. An osmotic device according to claim 15, wherein the first environment of use is the gastric region and the second environment of use is farther down the gastrointestinal tract of a mammal.

17. An osmotic device according to claim 1, wherein the first and second active agents are released into the same environment of use.

18. An osmotic device according to claim 1, wherein the controlled delivery of one or more active agents includes one or more of pH-dependent, pH-independent, diffusion controlled, dissolution controlled, pseudo-zero order, zero-order, pseudo-first order, first-order, second-order, rapid, slow, delayed, timed, and sustained delivery.

19. An osmotic device according to claim 1, wherein at least a portion of the polymer coat dissolves or erodes in fluid present in an environment of use after the external coat has at least partially dissolved in an environment of use.

20. An osmotic device according to claim 1, wherein the polymer coat is one or more of soluble in the same environment of use in which the external coat is soluble, and soluble in the same environment of use in which the core is soluble.

21. An osmotic device according to claim 1, wherein the semipermeable membrane comprises a plasticizer and one or more of a cellulose ether, cellulose ester and cellulose-ester-ether.

22. An osmotic device according to claim 1, wherein the external coat further comprises poly(vinylpyrrolidone).

23. An osmotic device according to claim 1, wherein the polymer coat further comprises one or more of talc and poly(ethylene glycol).

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(Added new claims 24-49)

~~antiparasitic, antiviral, local anesthetic, antifungal, amoebicidal, trichomonocidal, analgesic, antiarthritic, antiasthmatic, anticoagulant, anticonvulsant, antidepressant, antidiabetic, antineoplastic, antipsychotic, neuroleptic, antihypertensive, muscle relaxant, depressant, hypnotic, sedative, psychic energizer, tranquilizer, antiparkinson, muscle contractant, anti-microbial, antimalarial, hormonal, contraceptive, sympathomimetic, diuretic, hypoglycemic, ophthalmic, electrolyte, diagnostic and cardiovascular agent.~~

- 35) (Previously presented) ~~The multi-layered osmotic device of claim 1, 24, 25, 26 or 27, wherein the first and second active agents are independently selected at each occurrence from the group consisting of pesticide, herbicide, insecticide, antioxidant, plant growth instigator, sterilization agent, catalyst, chemical reagent, food product, nutrient, cosmetic, vitamin, sterility inhibitor, fertility instigator, microorganism, flavoring agent, sweetener, and cleansing agent.~~
- 36) (Currently amended) A multi-layered osmotic device for the controlled delivery of one or more active agents to one or more environments of use wherein the osmotic device comprises:
- a) a compressed core comprising a first active agent and at least one osmotic agent for controlled and continuous release of the first active agent;
 - b) a semipermeable membrane surrounding the core and having at least one preformed passageway therein;
 - c) an inert, completely erodible or water soluble polymer coat partially or completely surrounding the semipermeable membrane and plugging the passageway in the semipermeable membrane and comprising poly(vinylpyrrolidone)-(vinyl acetate) copolymer and a second polymer; and
 - d) an external coat applied to and covering the inert polymer coat and comprising a second active agent for immediate release of the second active agent, wherein the first active agent is released from the core after the polymer coat has partially or completely dissolved or eroded, and the first and second active agents are released into the same or different environments of use.
- 37) (Canceled)

- 38) (Previously presented) The multi-layered osmotic device of claim 36, wherein the semipermeable membrane comprises a plasticizer and one or more of a cellulose ether, cellulose ester and cellulose-ester-ether.
- 39) (Previously presented) The multi-layered osmotic device of claim 38, wherein the polymer coat further comprises one or more of talc and poly(ethylene glycol).
- 40) (Previously amended) The multi-layered osmotic device of claim 1, 24, 25, 26 or 27, wherein the inert, completely erodible or water soluble polymer coat comprises at least two different polymers.
- 41) (Previously presented) The multi-layered osmotic device of claim 1, 24, 25, 26 or 27, wherein the delivery of the first active agent is delayed with respect to delivery of the second active agent.
- 42) (Previously presented) The multi-layered osmotic device of claim 1, 24, 25, 26 or 27, wherein the first active agent is ranitidine and the second active agent is a combination of ranitidine and cisapride.
- 43) (Previously presented) The multi-layered osmotic device of claim 1, 24, 25, 26 or 27, wherein the first active agent is pseudoephedrine and the second active agent is astemizole.
- 44) (Previously presented) The multi-layered osmotic device of claim 1, 24, 25, 26 or 27, wherein the first active agent is pseudoephedrine and the second active agent is loratadine.
- 45) (Previously presented) The multi-layered osmotic device of claim 1, 24, 25, 26 or 27, wherein the first active agent is diltiazem and the second active agent is enalapril.
- 46) (Previously presented) The multi-layered osmotic device of claim 1, 24, 25, 26 or 27, wherein the first and second active agents are theophylline.
- 47) (Previously presented) The multi-layered osmotic device of claim 1, 24, 25, 26 or 27, wherein the first active agent is a decongestant and the second active agent is an antihistamine.
- 48) (Previously presented) The multi-layered osmotic device of claim 1, 24, 25, 26 or 27, wherein the first active agent is a first antihypertensive agent and the second active agent is a different second antihypertensive agent.

- 49) (Previously presented) The multi-layered osmotic device of claim 1, 24, 25, 26 or 27, wherein the first active agent is a gastric acid inhibitor and the second active agent is a gastrointestinal emptying adjunct agent.
- 50) (Currently amended) A multi-layered osmotic device for the controlled delivery of one or more active agents to one or more environments of use wherein the osmotic device comprises:
- a) a compressed core comprising a first active agent and at least one osmotic agent for controlled and continuous release of the first active agent;
 - b) a semipermeable membrane surrounding the core and having at least one preformed passageway therein;
 - c) an inert, completely erodible or water soluble polymer coat partially or completely surrounding the semipermeable membrane and plugging the at least one preformed passageway in the semipermeable membrane, wherein the inert, completely erodible or water soluble polymer coat comprises poly(vinylpyrrolidone)-(vinyl acetate) copolymer; and
 - d) an external coat applied to and covering the inert polymer coat and comprising a second active agent for release of the second active agent, wherein the first active agent is released from the core after the polymer coat has partially or completely dissolved or eroded, and the first and second active agents are released into the same or different environments of use.
- 51) (Previously amended) The multi-layered osmotic device of claim 50, wherein the inert, completely erodible or water soluble polymer coat further comprises a second polymer.
- 52) (Previously presented) The multi-layered osmotic device of claim 50, wherein the semipermeable membrane comprises a plasticizer and one or more of a cellulose ether, cellulose ester and cellulose-ester-ether.
- 53) (Currently amended) A multi-layered osmotic device for the controlled delivery of one or more active agents to one or more environments of use wherein the osmotic device comprises:
- a) a compressed core comprising a first active agent and at least one osmotic agent for controlled and continuous release of the first active agent;

- b) ~~a semipermeable membrane surrounding the core and having at least one preformed passageway therein;~~
 - c) ~~an inert, completely erodible or water soluble polymer coat partially or completely surrounding the semipermeable membrane and plugging the at least one preformed passageway in the semipermeable membrane and comprising poly(vinylpyrrolidone)-(vinyl acetate) copolymer; and~~
 - d) ~~an external coat applied to and covering the inert polymer coat and comprising a second active agent for immediate, rapid, delayed, slow, sustained, pseudo-first order, pseudo-zero order, timed, controlled or combination thereof release of the second active agent, wherein the first active agent is released from the core after the polymer coat has partially or completely dissolved or eroded, and the first and second active agents are released into the same or different environments of use.~~
- 54) (Previously amended) ~~The multi-layered osmotic device of claim 53, wherein the inert, completely erodible or water soluble polymer coat further comprises a second polymer.~~
- 55) (Previously presented) ~~The multi-layered osmotic device of claim 53, wherein the semipermeable membrane comprises a plasticizer and one or more of a cellulose ether, cellulose ester and cellulose-ester-ether.~~